canadian hospital specialties ltd.

September 1, 1999

Dockets Management Branch
(HFA – 305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Dear Sir/Madam:

RE: Federal Register Vol. 64, No. 93 Friday, May 14, 1999
Foreign Establishment Registration and Listing.

Canadian Hospital Specialties Ltd. (CHS) does not object to the requirement for foreign establishments to register with the US FDA. In fact, under Canada's device license requirements, manufacturers, both foreign and domestic, are essentially registered with Health Canada. We also recognize the desire of the FDA to establish a database of foreign establishments exporting medical devices to the US. CHS does find objectionable, however, the requirement to designate a United States Agent for purposes of importing a medical device into the US. The responsibilities of the US agent described in the proposed amendment would include submitting annual certifications, registration and listing information as well as premarket notifications, in addition to acting as official correspondent.

This requirement for a US agent would be a disadvantage to us as a Canadian company trying to do business in the US. We would have to employ a firm to act as a designated agent, and a firm of this calibre would likely charge substantial fees for their services. Since we would mainly employ multiple US distributors to sell our products, it is unlikely we would employ these same distributors to act as the US agent since they (distributors) would be privy to confidential information required of the agent.

The requirement for a US agent also will, in our opinion, add one more obstacle to communications between FDA and ourselves as manufacturers, which will only add to delays, and slow down rapid exchange of information should that be required. If FDA is concerned with communications and/or the ability to communicate with a foreign manufacturer, albeit a legitimate concern, it should be less of a problem with Canadian manufacturers. Canada and the US share many similarities that facilitate communications between manufacturers and FDA. Language, culture, business ethics, time zones, communications capabilities, are essentially on a par between both countries.

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The proposed amendment stipulates a US agent will be responsible for submitting documents such as premarket notifications. We presume this responsibility is a desire to facilitate communications between FDA and the foreign establishment. However, should communications between FDA and Canadian manufacturers be optimal, the designated agent requirement might not be necessary.

We suggest that the amendment be promulgated to require foreign establishment registration but that the US Agent requirement be implemented based on the likelihood of communication problems with certain regions. Regions that would not present a problem could be exempt from this particular requirement. FDA might also consider staying the US Agent with countries where there is not a reciprocal requirement.

We trust these comments will be taken under consideration and eagerly await the decision of the FDA on this proposed amendment.

Sincerely,

CANADIAN HOSPITAL SPECIALTIES LTD.

David Enns
Vice President

DE/jh

cc Ms. Birgit Mattiesen, Canadian Embassy, Washington
Kevin Murray, Medec Canada
Debbie Walker, Ontario Exports Inc., Toronto

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